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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,728	12/05/2003	George F. Kick	ONSET.002A	1724

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EXAMINER

SIMPSON, SARAH A

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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05/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,728	Applicant(s) KICK ET AL.	
	Examiner SARAH A. SIMPSON	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-29,47,49-51,60,62-64,72 and 74-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27-29,47,49-51,60,62-64,72 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/06/2004; 6/17/2005; 12/13/2006; 1/25/2007;</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>8/01/2007</u> | |

DETAILED ACTION

1. Prosecution on the merits of this application is reopened, all previously indicated allowable claims are withdrawn. Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, and 74-76 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, and 74-76** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Eversull et al. (WO 03/090834 A2)** in view of **Gill et al. (EP 0206553)** in view of **Nishtala et al. (US 2001/0012950 A1)**.

Eversull et al. discloses a method of providing percutaneous access to a gastrointestinal or urogenital tract including the steps of inserting a guidewire into the tract, percutaneously inserting an expandable tubular structure (120) over the guidewire into the tract, providing a constraining jacket (180) with perforations (186) for constraining an expandable access cannula which is insertable into gastrointestinal or urogenital tracts and expanding the tubular structure. Eversull discloses that the distal end of the expandable cannula is beveled (page 15, lines 3-7). The outer sheath can be attached to the expandable cannula (page 20, lines 10-12), or it can be a completely separate sheath. It is not specifically disclosed that the device is inserted into the renal collection system. However, the examiner contends that either the areas of insertion disclosed by Eversull meets this limitation, or in the alternative, it would have been obvious to have used it in such an area, as it was known to use similar expandable cannulas in this area as taught by Gill. Furthermore, Eversull discloses a fluid or an instrument may be introduced into the tubular structure such that it expands until it

pushes radially outwardly (pages 20-21, lines 20-24, 1-2, & 6-9). Eversull fails to disclose wherein the inflated device is a balloon catheter.

However, Nishtala et al. teaches a balloon catheter loaded into a sheath in the renal collection system, which is inflated to an appropriate pressure. This pressure provides radial force to dilate the tract and acts as an actuation device to the dilating elements. The balloon can then be removed for insertion of another, different sized balloon or to remove the dilator ([0004]; [0081]; [0082]).

Given the teachings of Nishtala et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of providing percutaneous access by inflating a balloon catheter to radially expand the tubular structure from a first smaller cross-sectional profile to a second, greater cross-sectional profile, and then removing the balloon following the expanding steps. Balloon catheters are commonly used and well known in the art to inflate structures such as tubes, sheaths, stents, etc. Balloons are preferable expanding devices as they are easy to use, cost effective, and allow a medical instrument to be expanded to a predetermined diameter.

5. **Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, and 74-76** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gill et al. (EP 0206553)** in view of **Eversull et al. (WO 03/090834 A2)** in view of **Nishtala et al. (US 2001/0012950 A1)**.

Gill discloses a method of providing percutaneous access to a renal collection system including the steps of inserting a guidewire into the system, percutaneously inserting an expandable tubular structure over the guidewire into the renal system; and

expanding the tubular structure. However, releasing the expanded tubular structure from a constraining tubular jacket by tearing the jacket along perforations is not disclosed. However, Eversull discloses that it was known to provide a constraining jacket with perforations for constraining an expandable access cannula which is insertable into gastrointestinal or urogenital tracts. Furthermore, Eversull discloses a fluid or an instrument may be introduced into the tubular structure such that it expands until it pushes radially outwardly (pages 20-21, lines 20-24, 1-2, & 6-9). It would have been obvious to have provided Gill with such a constraining tubular jacket in order to prevent the unintended expansion of the expandable access cannula during insertion and until expansion is desired. Gill fails to disclose wherein the inflated device is a balloon catheter.

However, Nishtala et al. teaches a balloon catheter loaded into a sheath in the renal collection system, which is inflated to an appropriate pressure. This pressure provides radial force to dilate the tract and acts as an actuation device to the dilating elements. The balloon can then be removed for insertion of another, different sized balloon or to remove the dilator ([0004]; [0081]; [0082]).

Given the teachings of Nishtala et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of providing percutaneous access by inflating a balloon catheter to radially expand the tubular structure from a first smaller cross-sectional profile to a second, greater cross-sectional profile, and then removing the balloon following the expanding steps. Balloon catheters are commonly used and well known in the art to inflate structures such as tubes,

sheaths, stents, etc. Balloons are preferable expanding devices as they are easy to use, cost effective, and allow a medical instrument to be expanded to a predetermined diameter.

Response to Argument

6. Applicant's arguments in view of amendment of claims 25, 47, 60, and 72, filed 1/18/2008, with respect to allowability have been fully considered. However, upon further consideration, the allowable claims have been withdrawn and a new ground(s) of rejection is made over Eversull et al. (WO 03/090834 A2) in view of Gill et al. (EP 0206553) in view of Nishtala et al. (US 2001/0012950 A1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4148

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 4148
8 May 2008

/Terrell L Mckinnon/
Supervisory Patent Examiner, Art Unit 4148